

FIG. 1

FIG. 2

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FOR THE INVENTOR'S EXCLUSIVE USE  
IN THE UNITED STATES OF AMERICA

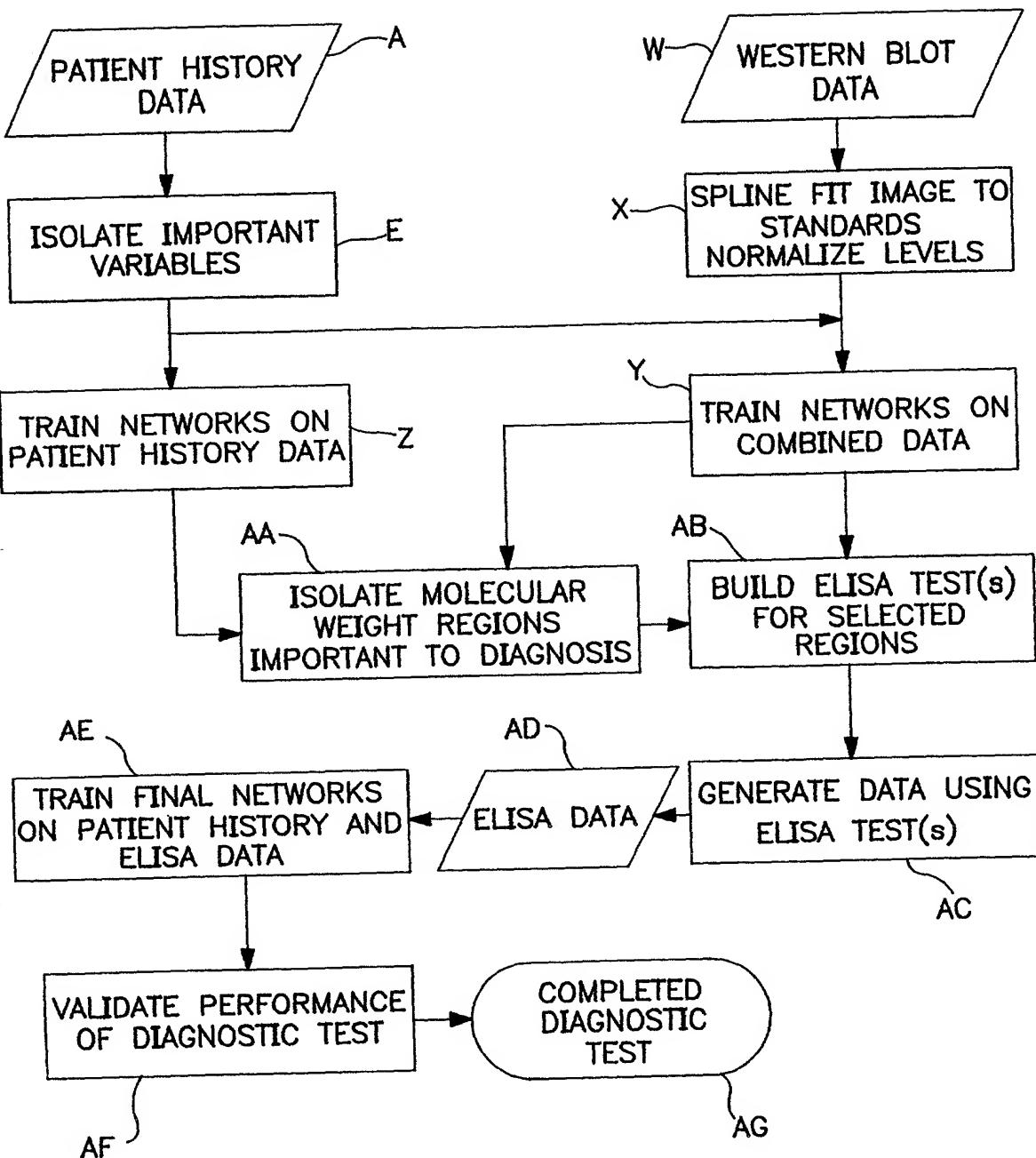
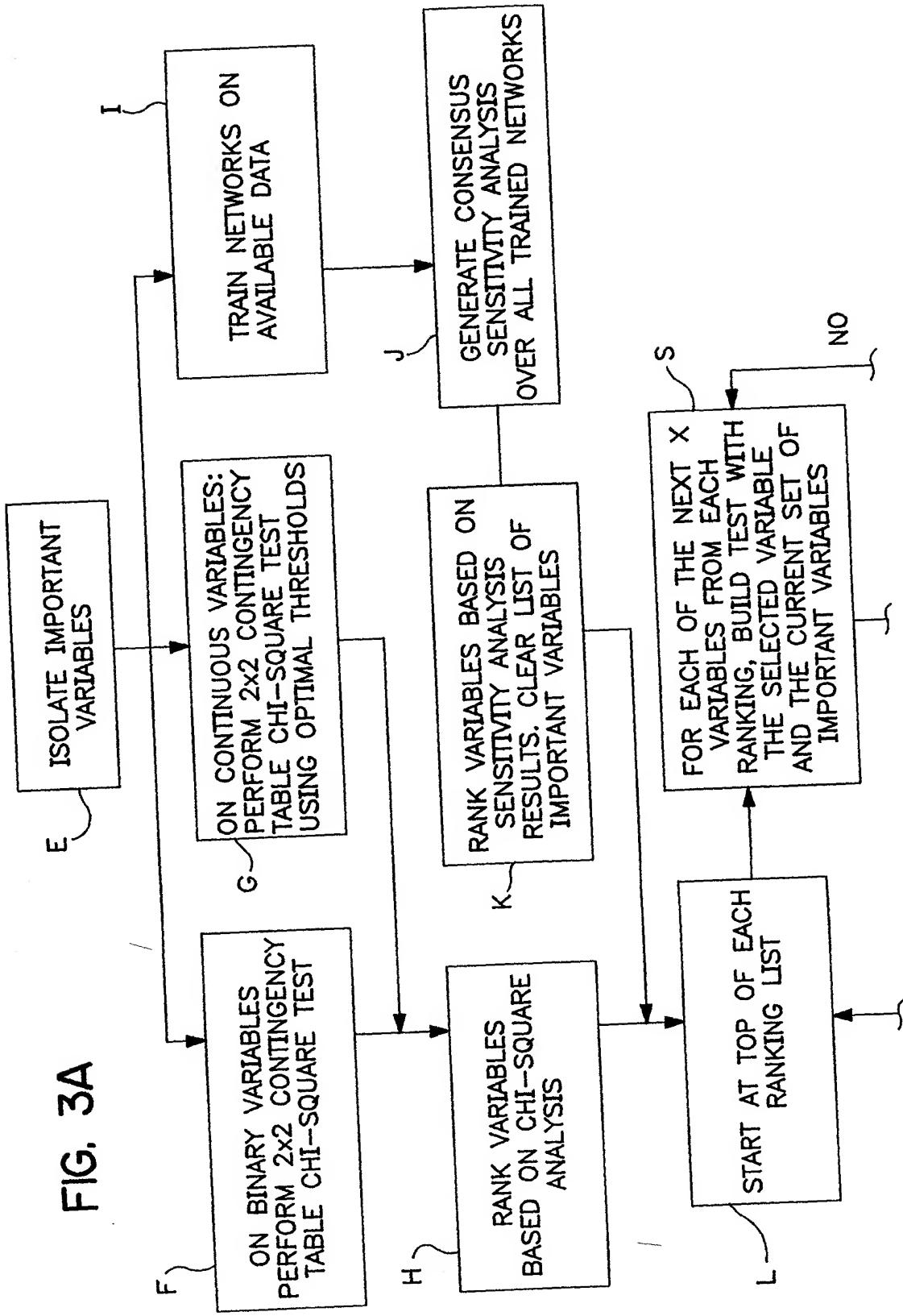


FIG. 3A



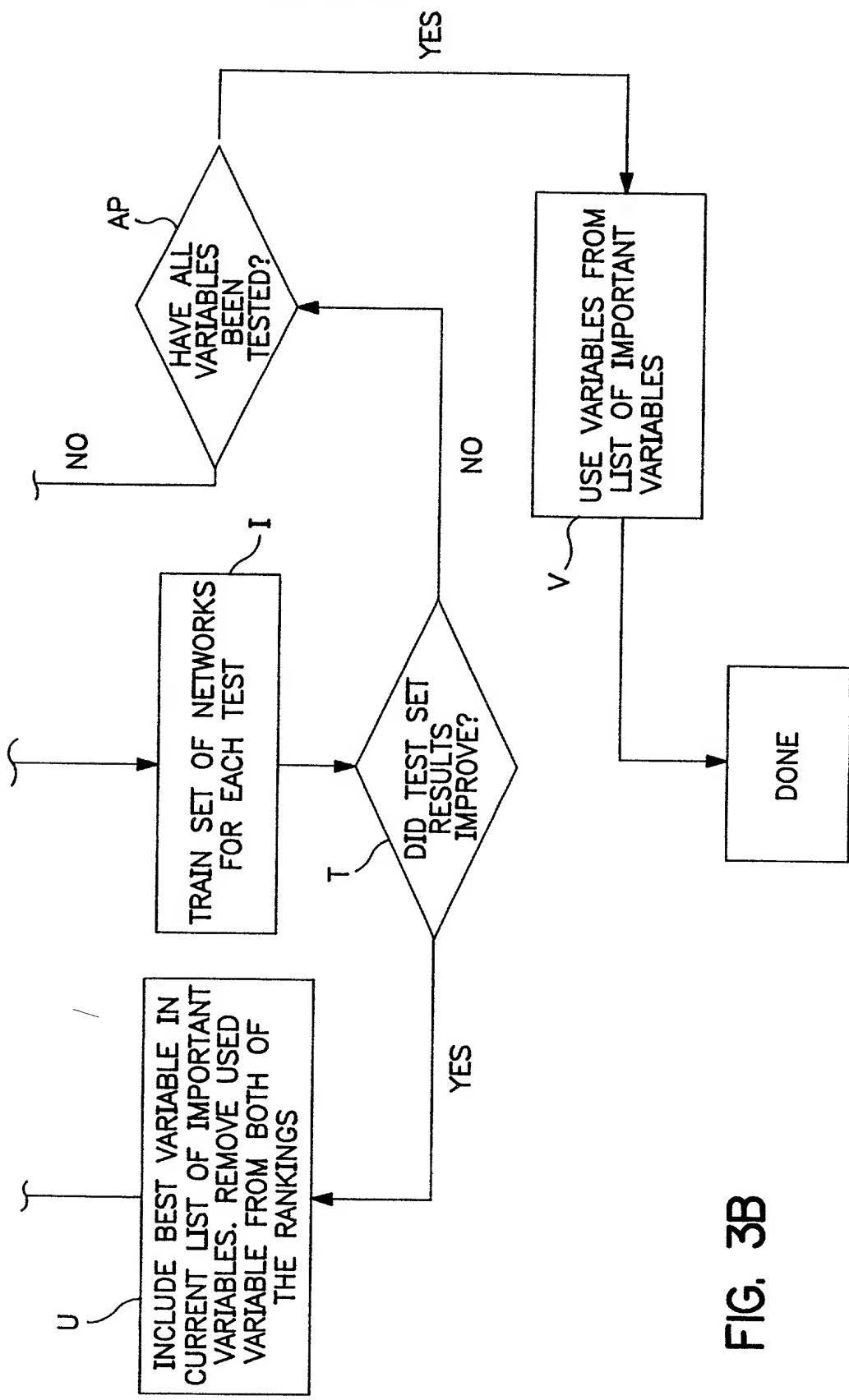


FIG. 3B

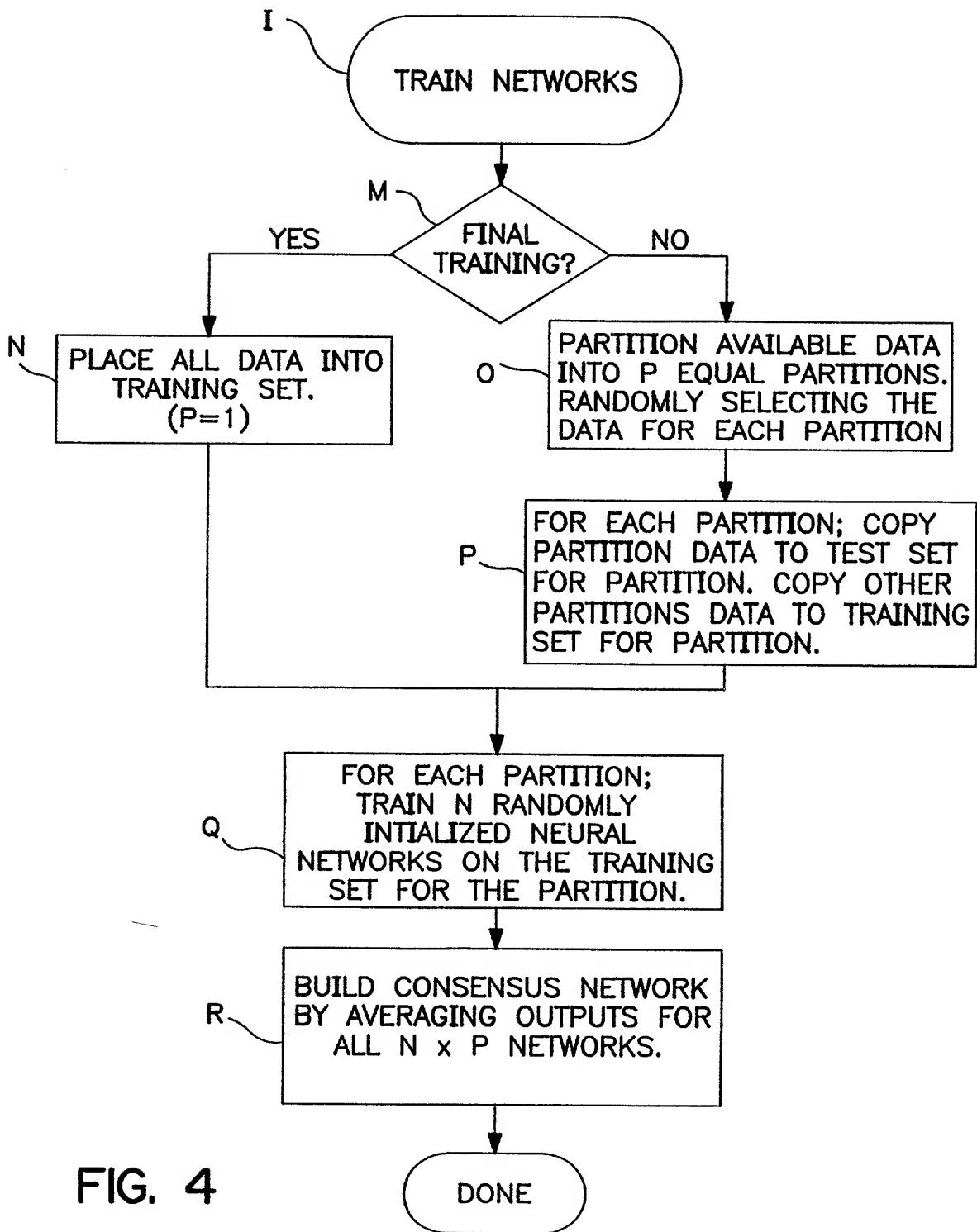


FIG. 4

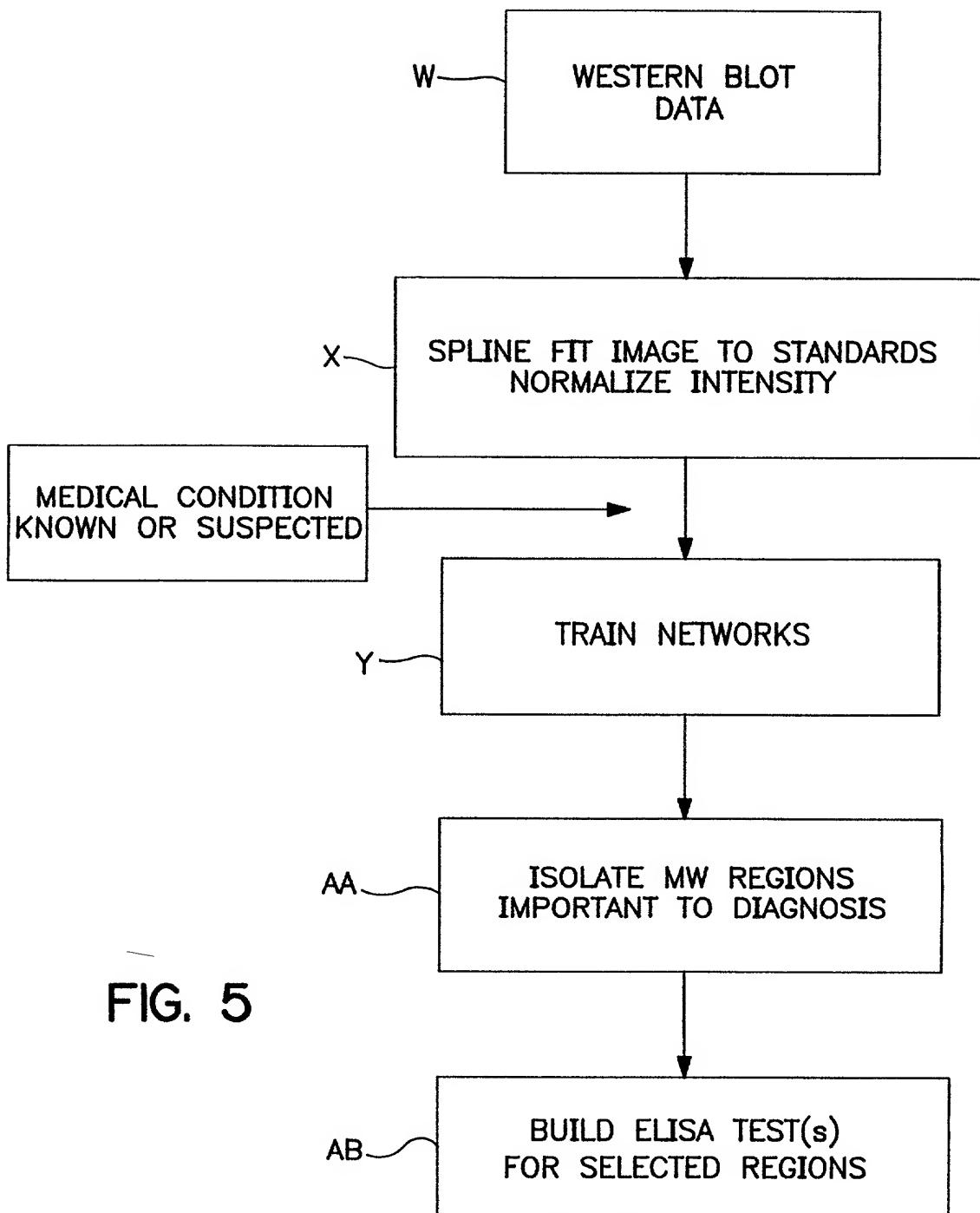


FIG. 5

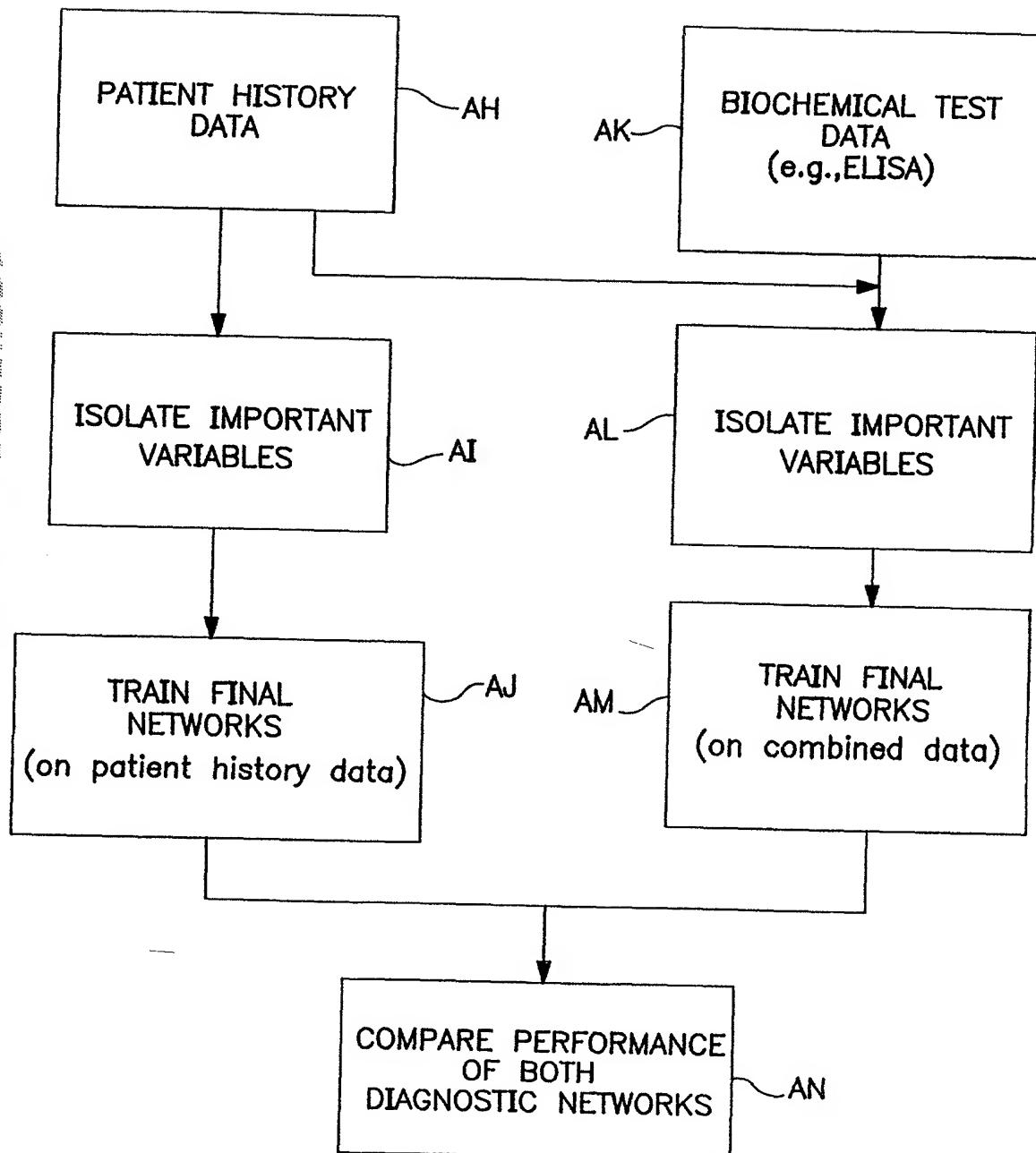


FIG. 6

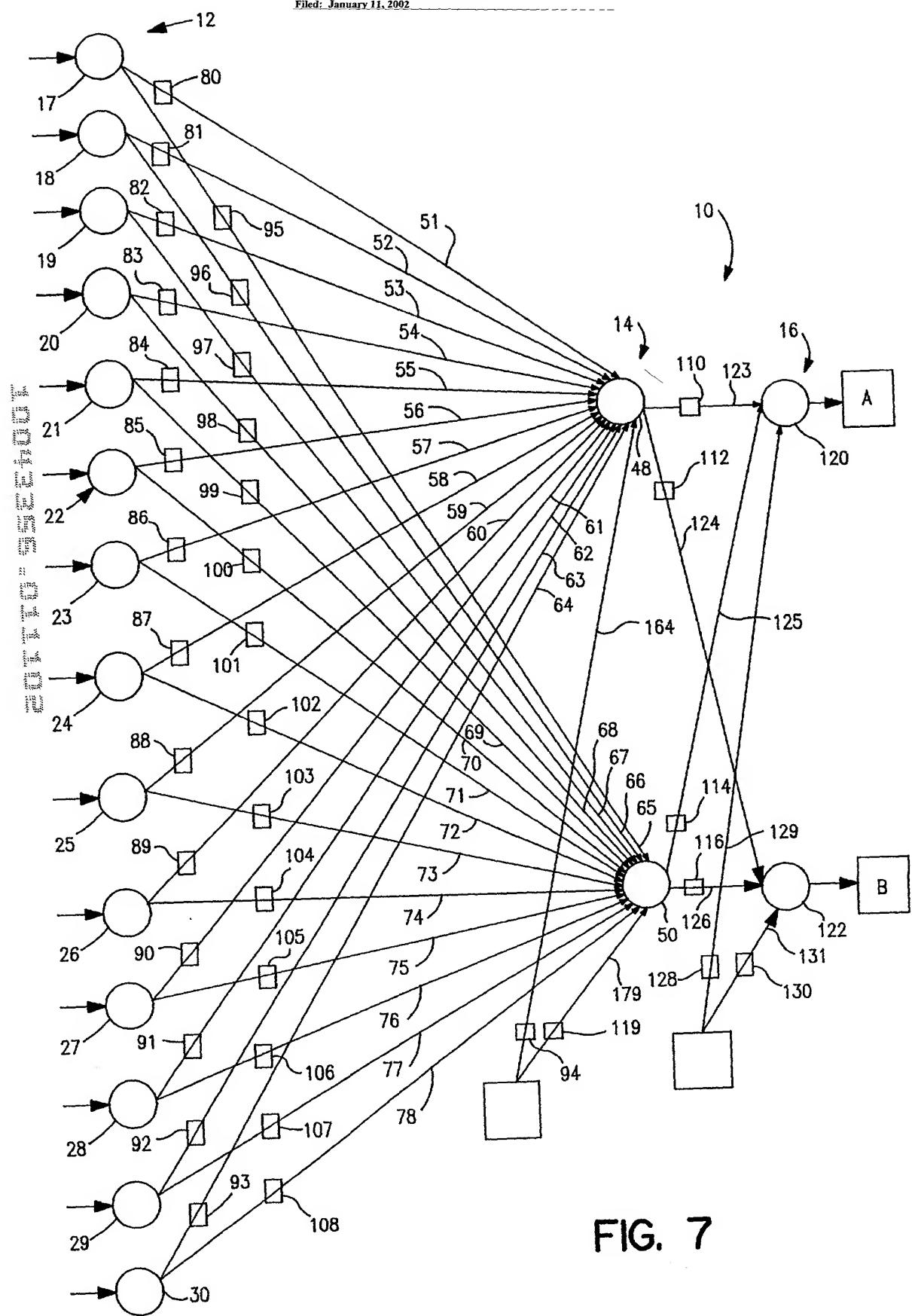


FIG. 7

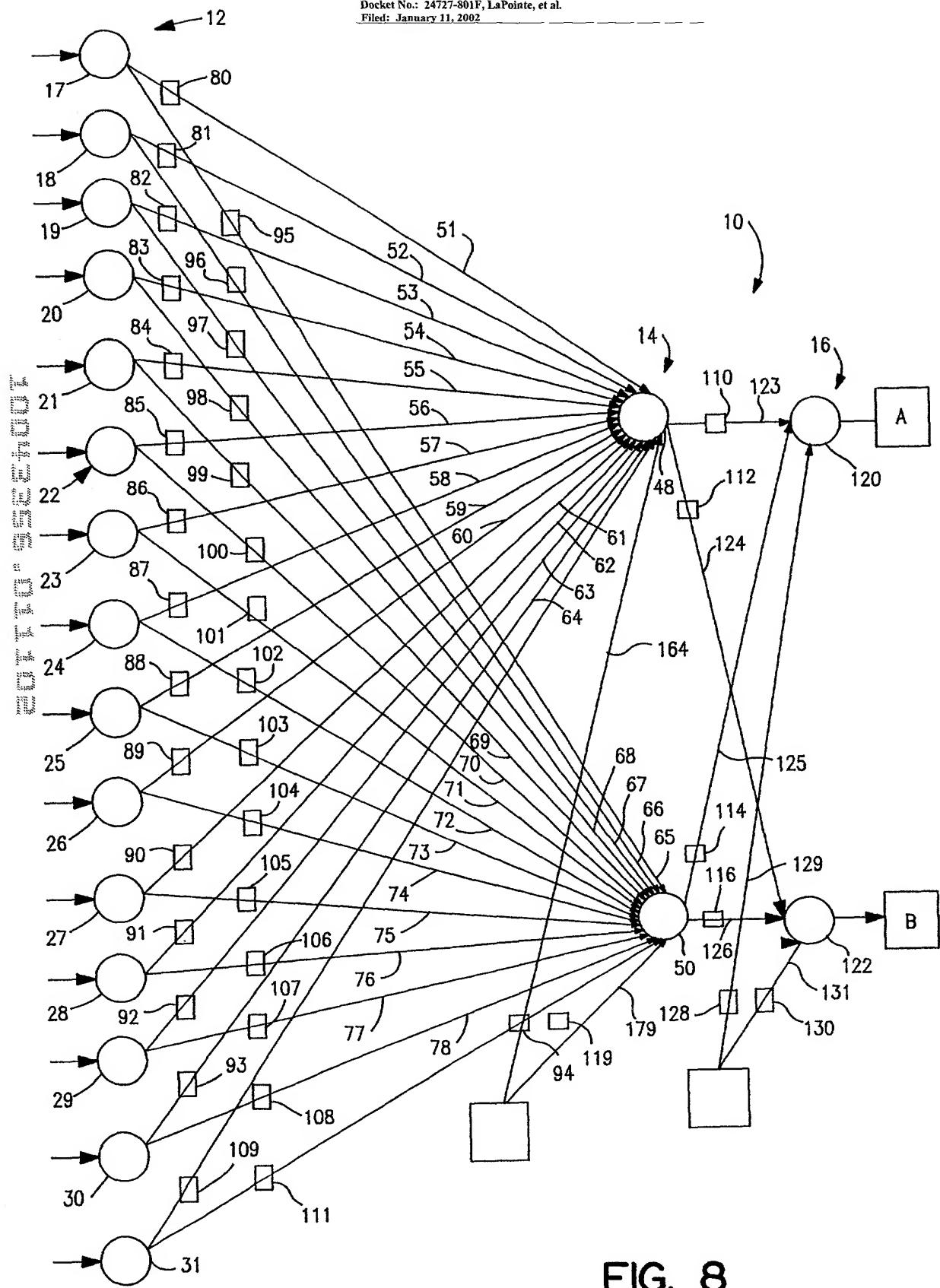


FIG. 8

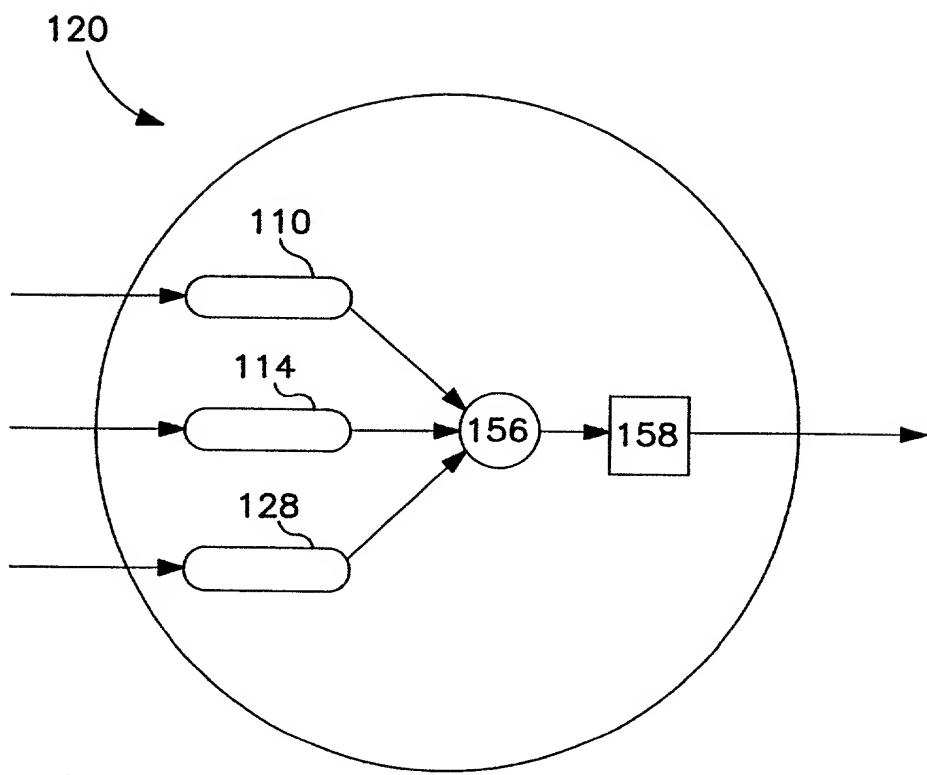


FIG. 9

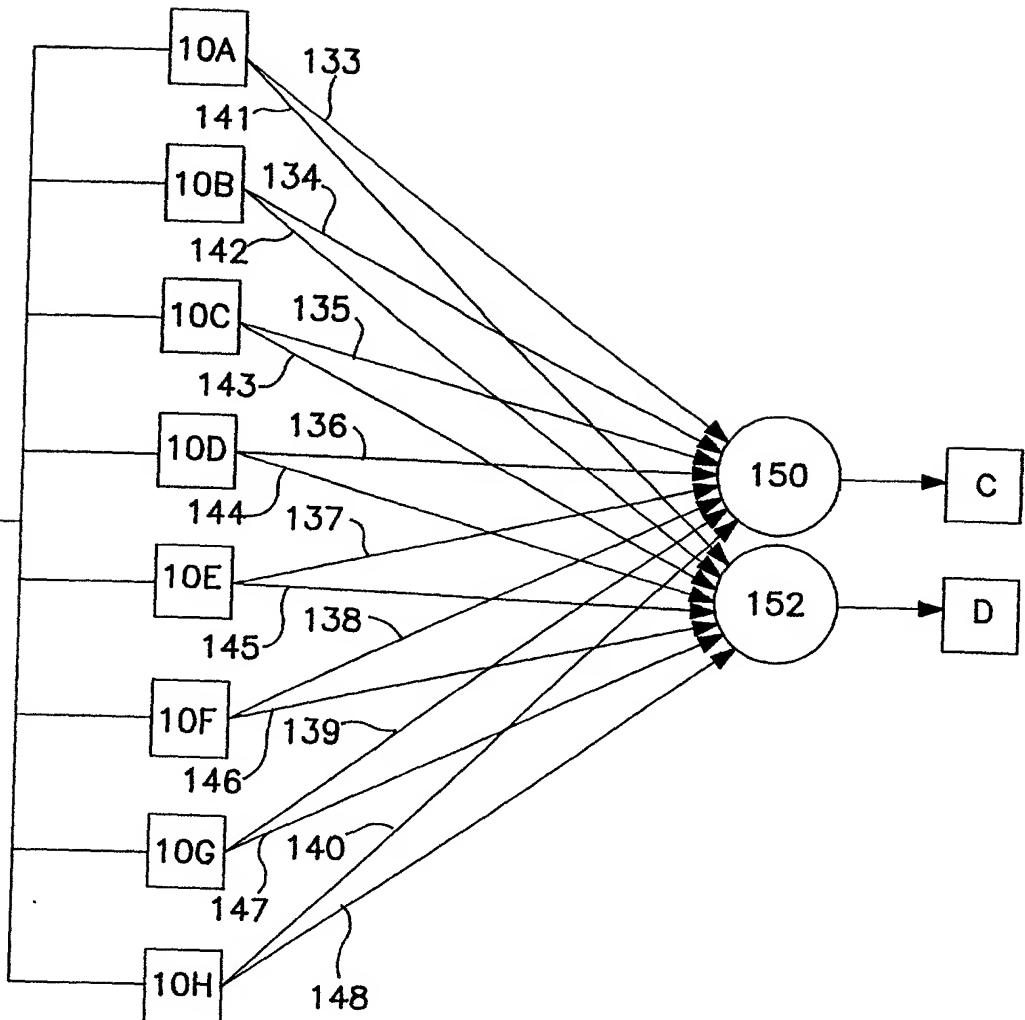


FIG. 10

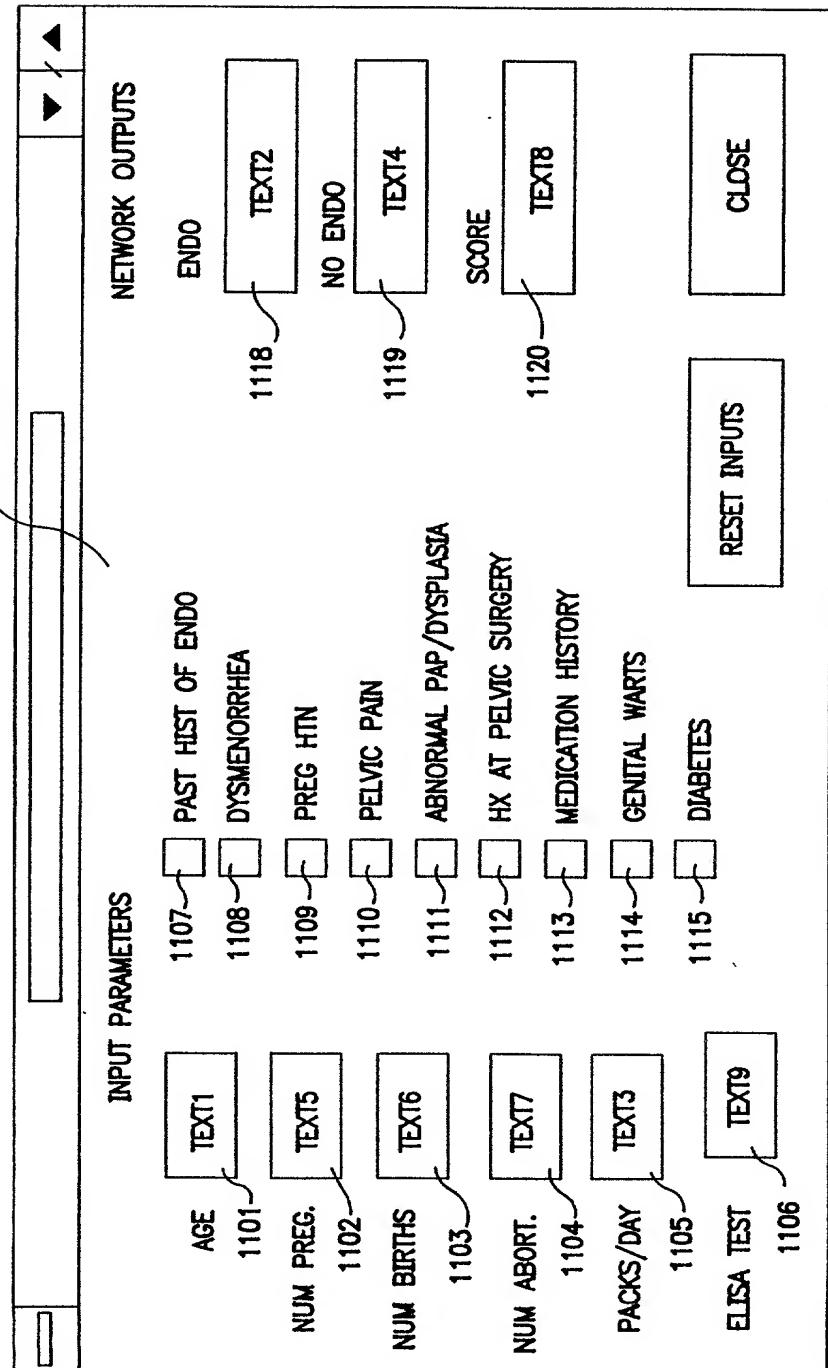


FIG. 11

PTDimp Windows Application-PTDin

File Record Options View Help

File: Current record: 1  
Number of records: 0

Lab ID #	
Patient Name:	
Pre-term Delivery Risk <34.6wks:	0.288432
Pre-term Delivery Risk <7 days:	0.001721
Pre-term Delivery Risk <14 days:	0.001544

Ready :

FIG. 12

Pre-Term Delivery Risk Assessment Software: Data Entry Screen

Lab ID #

**PATIENT INFORMATION**

Name(last) <input type="text"/>	First <input type="text"/>	M <input type="checkbox"/>	Ethnic origin: <input type="checkbox"/> Caucasian <input type="checkbox"/> African American <input type="checkbox"/> Asian <input type="checkbox"/> Hispanic <input type="checkbox"/> Native American <input type="checkbox"/> Other
DOB <input type="text"/> mm/dd/yy	Marital status: <input type="checkbox"/> Married <input type="checkbox"/> Single <input type="checkbox"/> Divorced/Separated <input type="checkbox"/> Widowed <input type="checkbox"/> Living with partner <input type="checkbox"/> Other		

**PATIENT HISTORY AND CLINICAL INFORMATION**

At the time of sampling, was the patient experiencing signs and symptoms of possible preterm labor?  YES  NO

If yes, please mark all that apply.

<input type="checkbox"/> Uterine contractions with or without pain Number/hr. <input type="checkbox"/> <1 <input type="checkbox"/> 1-3 <input type="checkbox"/> 4-6 <input type="checkbox"/> 7-9 <input type="checkbox"/> 10-12 <input type="checkbox"/> >12	<input type="checkbox"/> Bleeding during the second or third trimester <input type="checkbox"/> Intermittent lower abdominal pain, dull, low back pain, pelvic pressure
<input type="checkbox"/> Vaginal bleeding <input type="checkbox"/> Trace <input type="checkbox"/> Med. <input type="checkbox"/> Gross	<input type="checkbox"/> Change in vaginal discharge—amount, color, or consistency <input type="checkbox"/> Menstrual-like cramping (with or without diarrhea)
<input type="checkbox"/> Patient is not "feeling right"	

Gestational Age: EGA by first trimester sono  ww.d EGA by LMP  ww.d EGA at sampling  ww.d

Previous Pregnancy: Please mark all that apply:	Current Pregnancy: G: <input type="text"/> P: <input type="text"/> A: <input type="text"/>
<input type="checkbox"/> Previous pregnancy: no complications	<input type="checkbox"/> Multiple Gestation <input type="checkbox"/> Twins <input type="checkbox"/> Triplets <input type="checkbox"/> Quads
<input type="checkbox"/> History of Preterm delivery If Yes, how many? <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> >2	<input type="checkbox"/> Uterine or cervical abnormality <input type="checkbox"/> Cerclage <input type="checkbox"/> Gestational Diabetes <input type="checkbox"/> Hypertensive Disorders
<input type="checkbox"/> History of Preterm PROM	
<input type="checkbox"/> History of incompetent cervix	
<input type="checkbox"/> History of PIH/preeclampsia	
<input type="checkbox"/> History of SAB prior to 20 wks.	

Cervical Status immediately following sample collection:  
Dilatation(cm)  <1  1  1-2  2  2-3  3  >3  Unk. Cervical consistency  Firm  Mod  Soft

Medications at Time of Test (check all that apply)

Antibiotics  Corticosteroids  Tocolytics  Insulin  Antihypertensives  None  Unknown

Qualitative fFN Elisa Test Results:  Positive  Negative

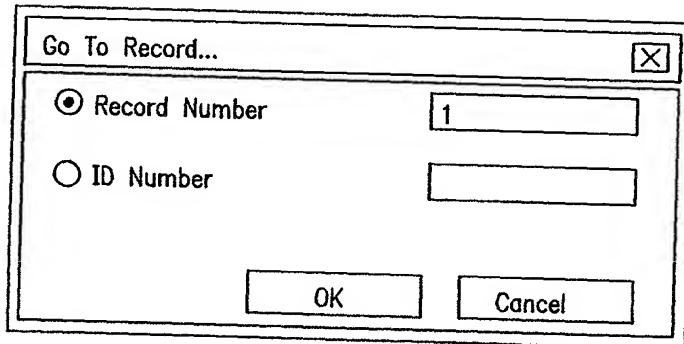


FIG. 14

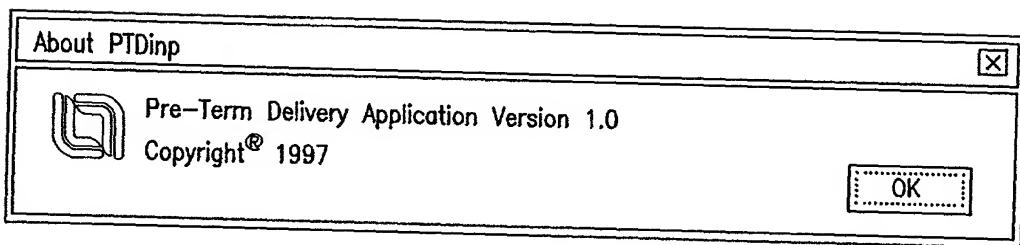


FIG. 15

Pre-Term Delivery Risk Assessment Software:  
Test Report Form

Lab ID #	
Patient Name:	
Pre-term Delivery Risk <34.6wks:	0.288432
Pre-term delivery Risk <7 days:	0.001721
Pre-term Delivery Risk <14 days:	0.001544

FIG. 16A

Pre-Term Delivery Risk Assessment Software: Data Entry Screen			Lab ID #
PATIENT INFORMATION			
Name(last) DOB mm/dd/yy	First M	Ethnic origin: <input type="checkbox"/> Caucasian <input type="checkbox"/> African American <input type="checkbox"/> Asian <input type="checkbox"/> Hispanic <input type="checkbox"/> Native American <input type="checkbox"/> Other Marital status: <input type="checkbox"/> Married <input type="checkbox"/> Single <input type="checkbox"/> Divorced/Separated <input type="checkbox"/> Widowed <input type="checkbox"/> Living with partner <input type="checkbox"/> Other	
PATIENT HISTORY AND CLINICAL INFORMATION			
At the time of sampling, was the patient experiencing signs and symptoms of possible preterm labor? <input type="checkbox"/> YES <input type="checkbox"/> NO If yes, please mark all that apply.			
<input type="checkbox"/> Uterine contractions with or without pain <input type="checkbox"/> Bleeding during the second or third trimester Number/hr. <input type="checkbox"/> <1 <input type="checkbox"/> 1-3 <input type="checkbox"/> 4-6 <input type="checkbox"/> Intermittent lower abdominal pain, dull, low back pain, pelvic pressure <input type="checkbox"/> 7-9 <input type="checkbox"/> 10-12 <input type="checkbox"/> >12			
<input type="checkbox"/> Vaginal bleeding <input type="checkbox"/> Change in vaginal discharge—amount, color, or consistency <input type="checkbox"/> Trace <input type="checkbox"/> Med. <input type="checkbox"/> Gross <input type="checkbox"/> Menstrual-like cramping (with or without diarrhea) <input type="checkbox"/> Patient is not feeling right			
Gestational Age: EGA by first trimester sono ww.d EGA by LMP ww.d EGA at sampling ww.d			
Previous Pregnancy: Please mark all that apply.		Current Pregnancy: G: P: A: <input type="checkbox"/> Previous pregnancy: no complications <input type="checkbox"/> History of Preterm delivery If Yes, how many? <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> >2 <input type="checkbox"/> History of Preterm PROM <input type="checkbox"/> History of incompetent cervix <input type="checkbox"/> History of PIH/preeclampsia <input type="checkbox"/> History of SAB prior to 20 wks.	
Cervical status immediately following sample collection: <input type="checkbox"/> Firm Dilatation(cm) <input type="checkbox"/> <1 <input type="checkbox"/> 1 <input type="checkbox"/> 1-2 <input type="checkbox"/> 2 <input type="checkbox"/> 2-3 <input type="checkbox"/> 3 <input type="checkbox"/> >3 Unknown Cervical consistency <input type="checkbox"/> Mod <input type="checkbox"/> Soft			
Medications at Time of Test (check all that apply) <input type="checkbox"/> Antibiotics <input type="checkbox"/> Corticosteroids <input type="checkbox"/> Tocolytics <input type="checkbox"/> Insulin <input type="checkbox"/> Antihypertensives <input type="checkbox"/> None <input type="checkbox"/> Unknown			
Qualitative fFN Elisa Test Results: <input type="checkbox"/> Positive <input type="checkbox"/> Negative			
Pre-term Delivery Risk <34.6wks: 0.288432 Pre-term Delivery Risk <7 days: 0.001721 Pre-term Delivery Risk <14 days: 0.001544			

FIG. 16B

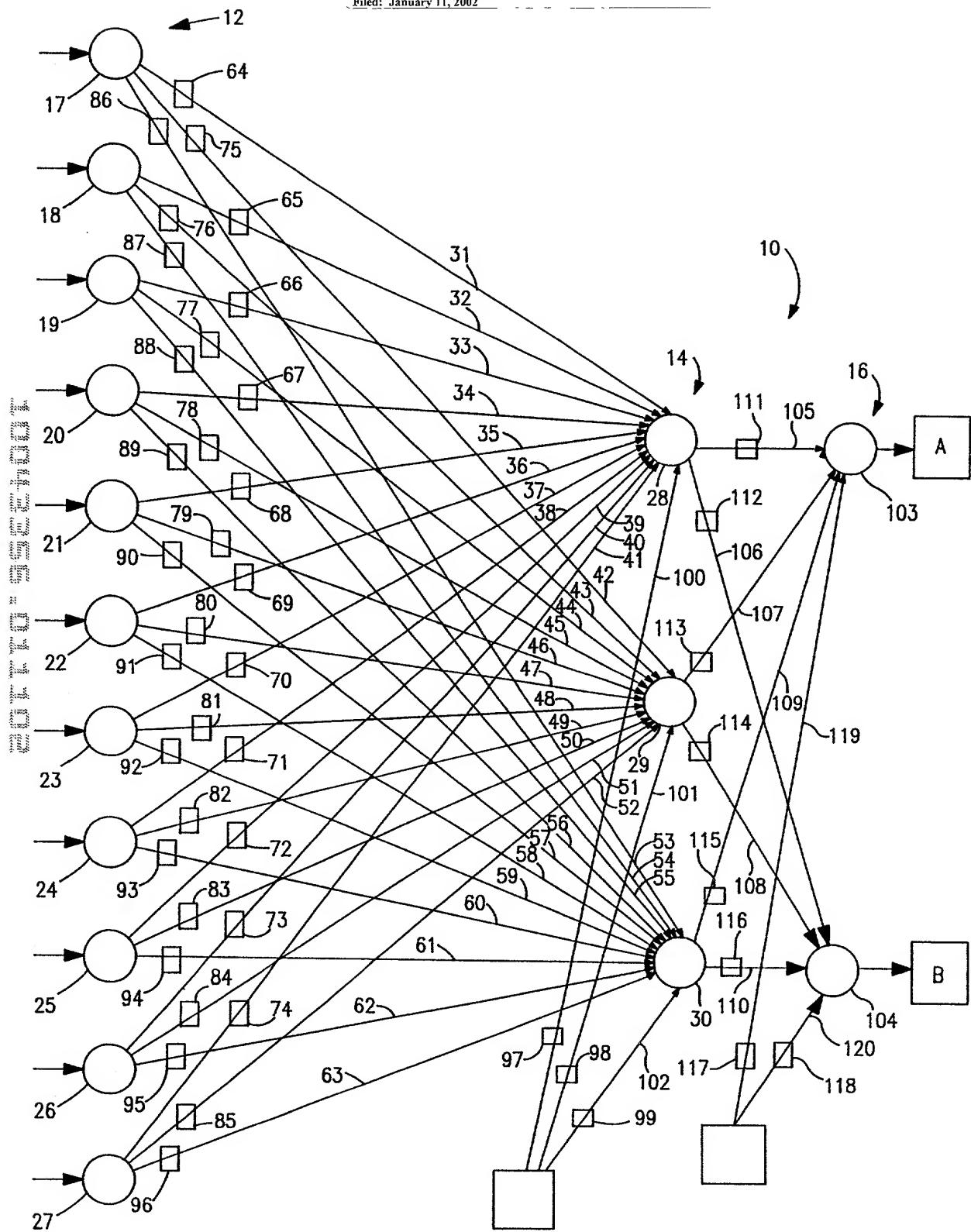


FIG. 17

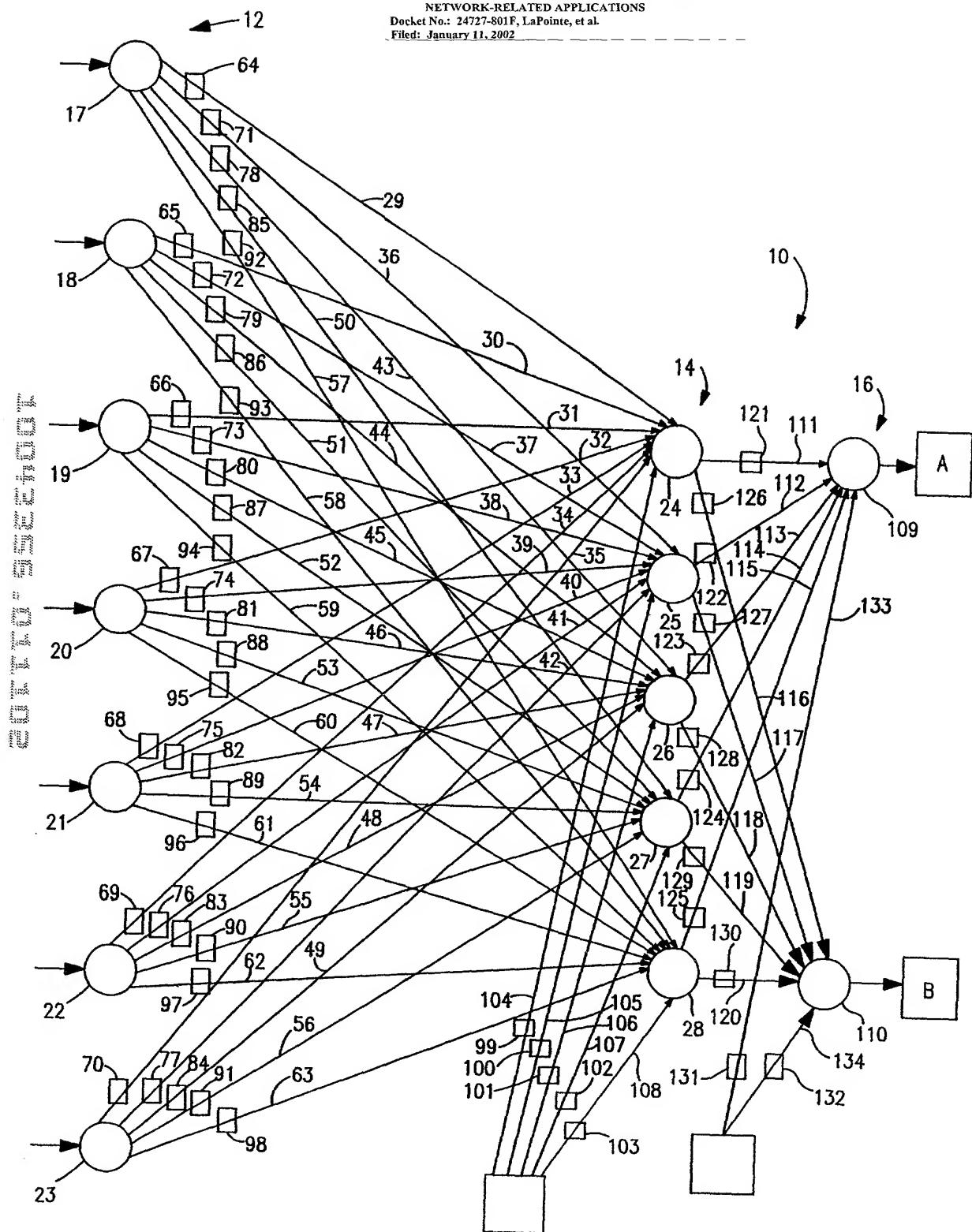


FIG. 18